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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/632,687	07/31/2003	Phillip Mark Hogarth	4602AR-2	2688
22442	7590	03/21/2007		
SHERIDAN ROSS PC 1560 BROADWAY SUITE 1200 DENVER, CO 80202			EXAMINER YU, MISOOK	
			ART UNIT	PAPER NUMBER
			1642	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		03/21/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

# Office Action Summary

Application No.

10/632,687

Applicant(s)

HOGARTH ET AL.

Examiner

MISOOK YU, Ph.D.

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 24 July 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 67-94 is/are pending in the application.
- 4a) Of the above claim(s) 67-73, 76, 80, and 82-94 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 74, 75, 77-79 and 81 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>4/24/06 and 7/24/06</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

This application contains claims 67-73 and 82-94 drawn to an invention nonelected with traverse. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 67-73, 76, 80, and 82-94 are withdrawn from further consideration for reason of record. Claims 67-94 are pending. Claims 74, 75, 77-79, and 81 are under consideration.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 74, 75, 77-79, and 81 are rejected under 35 U.S.C. 102(b) as being anticipated by Peltz et al., The Journal of Immunology, vol. 141, pages 1891-1896.

Claims 74, 75, 77-79, and 81 are drawn to an isolated polypeptide comprising an extracellular region of a native FcγRII receptor and a fusion component, wherein a fusion component is a carbohydrate in claim 75, the polypeptide is soluble in claim 77, in pharmaceutical diluent.

Applicant argues the native N-linked carbohydrates forms of sFcTRII would not be understood by the person skilled in the art as constituting a "fusion component" in

Art Unit: 1642

the context of the present invention. Applicant argues that the term "fusion component" would be understood by the person skilled in the art as referring to something that is foreign to the "Fc binding component", and the specification, at page 16, lines 25-35, states that augmentation of the Fc binding component "is achieved by adding a peptide, polypeptide or other molecule which is well tolerated in an animal.

These arguments have been fully considered but found unpersuasive because applicant arguments are not commensurate in scope of the claims. Claim 75 says that one embodiment of the term "a fusion component" in claim 74 is "carbohydrates". The specification as originally filed does not stipulate that "FcγRII carrying N-linked oligosaccharides at one and both of the two N-linked glycosylation expressed in the mammalian cell expression systems.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 75 and 79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peltz et al., (cited above) in view of Yeh et al., Proc. Natl. Acad. Sci. 1992 Mar 1;89(5):1904-8.

Claim 75 and 79 are interpreted as drawn to a polypeptide comprising an extracellular region of a native FcγRII receptor linked to human serum albumin (HSA).

Applicant argues that a reasonable expectation of success producing a biologically active fusion protein comprising FcγRII and HAS is not expected because HAS is a big molecule and FcγRII and CD4 are dissimilar.

This argument has been fully considered but found unpersuasive. As stated above, Peltz et al., teach a polypeptide comprising an extracellular region of a native FcγRII receptor. Peltz et al., do not teach HSA. However, Yeh et al., teach HAS has remarkably long half-life, together with its wide in vivo distribution and its lack of enzymatic or immunological functions” and therefore “fusion of bioactive peptides to HAS is a plausible approach toward the design and recovery” of secreted therapeutic.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to combine the teachings of Peltz et al., and Yeh et al., to arrive at the fusion of soluble FcγRII linked to HSA as taught by Yeh et al., with a reasonable expectation of success to make a fusion protein, given the high skill in the recombinant DNA technology of making a fusion protein as disclosed by Yeh et al. One of ordinary skill would have been motivated to make the claimed fusion protein given the advantage of the fusion protein as stated in Yeh et al.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

Art Unit: 1642

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 571-272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

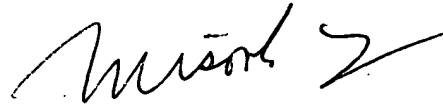
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MISOOK YU, Ph.D.

Application/Control Number: 10/632,687  
Art Unit: 1642

Page 6

Primary Examiner  
Art Unit 1642

A handwritten signature in black ink, appearing to read "Misook Yu", followed by a long horizontal flourish.

MISOOK YU  
PRIMARY EXAMINER